

**FOOD AND DRUG ADMINISTRATION (FDA)**  
Center for Drug Evaluation and Research (CDER)

***Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) Meeting***

FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)

White Oak Conference Center, Silver Spring, Maryland

March 28 – 29, 2012

**AGENDA**

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*The committee will discuss the role of cardiovascular assessment in the pre-approval and post-approval settings for drugs and biologics developed for the treatment of obesity.*

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<b>Day 1: Wednesday, March 28, 2012</b>
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8:00 a.m.	Call to Order and Introduction of Committee	<b>Abraham Thomas, M.D., M.P.H., FACP</b> Chairperson, EMDAC
8:05 a.m.	Conflict of Interest Statement	<b>Paul T. Tran, R.Ph</b> Designated Federal Officer, EMDAC
8:15 a.m.	Introduction/Background Overview of Day 1 Agenda	<b>Eric C. Colman, M.D.</b> Deputy Director Division of Metabolism and Endocrinology Products (DMEP) Office of Drug Evaluation (ODE) II Office of New Drugs (OND), CDER, FDA
8:25 a.m.	<b>FDA PRESENTATIONS</b>	
	FDA 2007 Draft Guidance for Industry: Developing Products for Weight Management	<b>Julie Golden, M.D.</b> Medical Officer DMEP, ODE II, OND, CDER, FDA
	Drug Utilization Trends of Anti-Obesity Products in the Outpatient Setting Y1991 - Y2011	<b>Vicky Borders-Hemphill, Pharm.D.</b> CDR, USPHS Commissioned Corps Division of Epidemiology II (DE-II)_ Office of Pharmacovigilance and Epidemiology (OPE) Office of Surveillance and Epidemiology (OSE), CDER, FDA
	Duration of Use – Anti-Obesity Drugs	<b>Christian Hampp, B.S. Pharm., Ph.D.</b> Visiting Associate/Epidemiologist Division of Epidemiology I (DE-I) OPE, OSE, CDER, FDA
9:10 a.m.	Clarifying Questions from Committee	

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**AGENDA (cont.)**

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9:30 a.m.     **GUEST SPEAKER PRESENTATION**

Pathophysiology of Obesity and  
Cardiovascular Diseases (CVD)

**Robert H. Eckel, M.D.**  
Professor in Medicine  
Director, Lipid Clinic  
University of Colorado

10:00 a.m.     Clarifying Questions from the Committee

10:15 a.m.     **BREAK**

10:30 a.m.     **SPEAKER PRESENTATION**

Obesity and Type 2 Diabetes

**William C. Knowler, M.D., Dr.PH**  
Chief, Diabetes Epidemiology and Clinical  
Research Section  
National Institute of Diabetes and Digestive  
and Kidney Diseases (NIDDK)  
National Institutes of Health (NIH)

11:00 a.m.     **GUEST SPEAKER PRESENTATION**

Look AHEAD (Action for Health in  
Diabetes) Trial

**Rena R. Wing, Ph.D.**  
Professor in Psychiatry & Human Behavior  
Director, Weight Control and Diabetes  
Research Center  
Brown Medical School

11:30 a.m.     Clarifying Questions from the Committee

12:00 p.m.     **LUNCH**

1:00 p.m.     **GUEST SPEAKER PRESENTATION**

Drugs to Treat Obesity: Cardiovascular and  
Other Risks

**George A. Bray, M.D., MACP, MACP**  
Boyd Professor  
Chief, Division of Clinical Obesity &  
Metabolism  
Pennington Biomedical Research Center  
Louisiana State University

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**1:30 p.m. FDA PRESENTATION**

Statistical Considerations in the Design of  
Cardiovascular Safety Trials to Rule Out a  
Pre-specified Cardiovascular Risk  
*Implications in Trials to Treat Obesity*

**Matthew Soukup, Ph.D.**  
Lead Mathematical Statistician  
Division of Biometrics VII  
Office of Biostatistics  
Office of Translational Sciences (OTS)  
CDER, FDA

**2:00 p.m. Clarifying Questions from the Committee**

**2:30 p.m. BREAK**

**2:45 p.m. FDA PRESENTATIONS**

Cardiovascular Outcomes Trials  
Experience with Rimonabant and  
Sibutramine

**Eric C. Colman, M.D.**

**3:30 p.m. Evaluating Cardiovascular Risk in New  
Antidiabetic Therapies to Treat Type 2  
Diabetes: Rationale and Key Features of The  
Guidance For Industry**

**Jean-Marc Guettier, M.D.**  
Diabetes Team Leader (Acting)  
DMEP, ODE II, OND, CDER, FDA

**4:00 p.m. Clarifying Questions from the Committee**

**5:00 p.m. ADJOURNMENT**

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**AGENDA (cont.)**

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**Day 2: Thursday, March 29, 2012**

8:00 a.m.	Call to Order and Introduction of Committee	<b>Abraham Thomas, M.D., M.P.H., FACP</b> Chairperson, EMDAC
8:05 a.m.	Conflict of Interest Statement	<b>Paul T. Tran, R.Ph</b> Designated Federal Officer, EMDAC
8:15 a.m.	FDA Remarks	<b>Eric C. Colman, M.D.</b> Deputy Director DMEP, ODE II, OND, CDER, FDA
8:30 a.m.	Open Public Hearing	
10:00 a.m.	<b>BREAK</b>	
10:15 a.m.	Questions to the Committee and Committee Discussion	
12:00 p.m.	<b>LUNCH</b>	
1:00 p.m.	Questions to the Committee and Committee Discussion	
3:00 p.m.	<b>BREAK</b>	
3:15 p.m.	Questions to the Committee and Committee Discussion	
5:00 p.m.	<b>ADJOURNMENT</b>	